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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,332	12/02/2003	Gregory M. Landes	ABGENIX.072A	5654
20995 7590 01/31/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER VANDERVEGT, FRANCOIS P	
			ART UNIT	PAPER NUMBER
			1644	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		01/31/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/31/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary

Application No.

10/726,332

Applicant(s)

LANDES ET AL.

Examiner

F. Pierre VanderVegt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 3-14, 17, 18 and 20-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 16, 19 and 29-31 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>20040301, 20060421</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application claims the benefit of the filing date of provisional application 60/430,724.

New claims 29-31 have been added.

Claims 1-31 are currently pending.

Election/Restrictions

1. Applicant's election of Group I in the reply filed on October 16, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 17, 18 and 20-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 16, 2006.
3. Applicant's election of the species SEQ ID NOs: 27 and 28 in the reply filed on October 16, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
4. Claims 3-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 16, 2006.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 1-2, 16, 19 and 29-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated human antibody having a heavy chain comprising the antigen binding sequence of SEQ ID NO: 27 and a light chain comprising the antigen binding sequence of SEQ ID NO: 28, does not reasonably provide enablement for an isolated human antibody having a heavy chain comprising the antigen binding sequence of SEQ ID NO: 27 and any undetermined light chain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

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Factors to be considered in determining whether undue experimentation is required are summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claims are broadly drawn to a human antibody or binding fragment thereof that binds to phospholipase A2 wherein the antibody comprises a heavy chain region selected from the group consisting of SEQ ID NOs: 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29 and 31. The claims do not specify the nature of the light chain, nor require that the light chain be obtained from the same antibody.

The elected species of the claimed invention comprises the heavy chain antigen-binding region disclosed in the specification as SEQ ID NO: 27. The specification further discloses only that the heavy chain region of SEQ ID NO: 27 associates with the elected light chain region of SEQ ID NO: 28 in order to make an anti-phospholipase A2 (PLA2) antibody. The chains are combined to compose the mAb designated 2.25 (Table 1 in particular). The specification does not disclose the association of SEQ ID NO: 27 with any of the other disclosed light chain sequences, much less with an undisclosed light chain sequence.

Janeway et al. (*Immunobiology* 4th Edition [1999] page 87, U on form PTO-892) teaches that the CDR1, CDR2 and CDR3 regions of the heavy and light chains determine antigen specificity of an antibody. Janeway treats CDR1, CDR2, and CDR3 of both the heavy and light chains equally and does not emphasize any one over the others. Further, Janeway clearly shows that not only are the CDRs important, but the intervening framework sequences contribute significantly to the 3-dimensional relationship of CDR1, CDR2, and CDR3 to one another, orienting the CDRs properly for forming the binding site. Together the heavy and light chains make up the antigen-binding site of the antibody. While the heavy chain defined by SEQ ID NO: 27 may interact with PLA2 in the absence of a light chain (although the instant specification does not show this), there is no indication to suggest to the artisan that the SEQ ID NO: 27 heavy chain would be able to combine with any light chain sequence other than SEQ ID NO: 28 in a 3-dimensional manner and still bind to PLA2, as the structure of any other light chain, including those of other instantly disclosed anti-PLA2 human antibodies, may interfere with SEQ ID NO: 27 and prevent binding to PLA2. There is no disclosure of the PLA2 epitopes that each of the disclosed anti-PLA2 antibodies of Table 1 binds to and it is not predictable based upon the state of the art that a light chain from an antibody from an anti-PLA2 antibody to a different epitope would be able to combine

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with the SEQ ID NO: 27 heavy chain and still bind to PLA2. Based upon the guidance provided in the instant disclosure and the paucity of working examples, the artisan would not be able to predict the structure of any compatible light chain other than SEQ ID NO: 28 that will form a PLA2 binding antibody.

In view of the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and the statute does not sanction this.

Conclusion


7. Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
January 3, 2006


DAVID A. SAUNDERS
PRIMARY EXAMINER